UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,243	11/12/2003	Solomon S. Steiner	PTD 103 CON (3)	6406

23579 7590 09/29/2005

PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE
SUITE 1200
ATLANTA, GA 30361

EXAMINER	
GEORGE, KONATA M	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,243	STEINER ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 16-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 16-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SAD

DETAILED ACTION

Claims 16-36 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on November 12, 2003 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Drawings

2. The drawing(s) filed under 37 CFR 1.184 or 1.152 are accepted by the examiner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 23-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No.

6,428,771 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the pending application and the patent are directed towards a microparticulate system for controlled delivery to the pulmonary system comprising microparticles having a diameter between 0.5 microns and 10 microns and are formulated to release the incorporated agent at a pH of 6.0 or greater under conditions present in the pulmonary system. The difference between the patent and the instant application is as follows, the instant application uses addition materials for forming the microparticles such as proteins, mixed amino acids, lipids and surface active agents.

4. Claims 23, 26-28, 31-33 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-7 and 10-12 of U.S. Patent No. 6,071,497. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the pending application and the patent are directed towards a microparticulate system for controlled delivery to the pulmonary system comprising microparticles having a diameter between 0.5 microns and 10 microns and are formulated to release the incorporated agent at a pH of 6.0 or greater under conditions present in the pulmonary system. The difference between the patent and the instant application is as follows, the instant application uses addition materials for forming the microparticles such as mixed amino acids, lipids and surface active agents.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Domb (US 5,188,837).

Claims 16 and 18 are directed towards a microparticle having a size between 0.5 to 10 microns formed from a material comprising a lipid.

Domb discloses in claim 1 a liposphere comprising a core, a phospholipid coating surrounding the core having an average particle size of between 0.3 and 250 microns. With respect to the pH of the material, it is the position of the examiner that since the prior art teaches the same material as claimed, then the material would have the same inherent properties of releasing the drug at the claimed pH. The prior art does not teach the exact particle size range.

It would have been obvious to one of ordinary skill in the art to realize that since the ranges of the instant invention overlap that the prior art ranges then the ranges are obvious to one of ordinary skill. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

6. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyes et al. (EP 0 257 915 A1).

Boyes et al. discloses a pharmaceutical formulation comprising a microcapsule having a polymeric wall material encapsulating a drug and a lipid-soluble surfactant mixed with the microcapsule or is incorporated within or coats the wall material of the microcapsule (abstract). Page 2, lines 54-55 teach that the particles range from 0.1 to 10 microns. With respect to the pH of the material, it is the position of the examiner that since the prior art teaches the same material as claimed, then the material would have the same inherent properties of releasing the drug at the claimed pH. The prior art does not teach the exact particle size range.

It would have been obvious to one of ordinary skill in the art to realize that since the ranges of the instant invention overlap that the prior art ranges then the ranges are obvious to one of ordinary skill. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

7. Claims 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debenedetti et al. (US 6,063,910).

Claims 16, 19 and 20 are directed towards a microparticle having a size between 0.5 to 10 microns formed from a material comprising proteins, particularly hydrophobic proteins.

Debenedetti et al. teaches in column 2, lines 24-15, 31-35 and 61-66, a method of forming protein microparticles, particularly hydrophobic protein microparticles (i.e. insulin, catalase, etc.) having a particle size of less than 10 microns. It is the position of the examiner that the recitation of protein includes all proteins, although it may be preferred that the protein is hydrophobic. Although the prior art does not disclose the microparticle releasing a drug at a pH of 6.0 or greater. The claim merely states that the microparticle is formed from a material that has that limitation, so any material that is claimed by applicant (i.e. proteins, amino acids, etc.) would have that limitation as well. The prior art does not teach the exact particle size range.

It would have been obvious to one of ordinary skill in the art to realize that since the ranges of the instant invention overlap that the prior art ranges then the ranges are obvious to one of ordinary skill. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

8. Claims 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugaya et al. (JP 363020301A).

Claims 16 and 21 are directed towards a microparticle having a size between 0.5 to 10 microns formed from a material comprising polysaccharides i.e. aliginate and chitosan.

Sugaya et al. discloses highly pure microparticles of chitosan having an average particle diameter of less than 10 microns (abstract) to be used as a carrier in the medical field. With respect to the pH of the material, since the prior art teaches the same material as claimed, then the material would release the drug at the claimed pH. The prior art does not teach the exact particle size range.

It would have been obvious to one of ordinary skill in the art to realize that since the ranges of the instant invention overlap that the prior art ranges then the ranges are obvious to one of ordinary skill. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyes et al. (EP 0 257 915 A1) as applied to claims 16 and 17 above, in view Hunt et al. (US 4,866,051).

Claim 22 is directed to a device for delivering the microparticle composition.

Boyes et al. discloses all that is recited in claim 22, except a cartridge for insertion into an inhaler. The prior art does not teach the exact particle size range.

Column 3, lines 23-27 of Hunt et al. teaches the use of inhalation cartridges comprising particles having a size below 10 microns.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teachings of Boyes et al. comprising dry particles in the invention

of Hunt et al. comprising inhalation cartridges for particles. The expected result would be facilitating delivering the microparticle via inhalation.

It would have been obvious to one of ordinary skill in the art to realize that since the ranges of the instant invention overlap that the prior art ranges then the ranges are obvious to one of ordinary skill. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Conclusion

10. Claims 16-36 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

Alton Pryor
Primary Examiner
A.U. 1616